Exhibit 86

UNITED STATES DISTRICT COURT
FOR THE
DISTRICT OF SOUTH CAROLINA

TAP PHARMACEUTICALS, INC., Plaintiff, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al., Defendants.	Civ. A. No. 3-97-969-19

BRIEF IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS

Plaintiff TAP Pharmaceuticals, Inc. ("TAP"), opposes the motion to dismiss under Rule 12(b)(1) filed by the United States Department of Health and Human Services ("HHS"), the Health Care Financing Administration ("HCFA"), and Palmetto Government Benefits Administrators ("Palmetto") (collectively, "Defendants") in the above-captioned action, in which TAP is suing for review of a Medicare local medical review policy ("LMRP") that arbitrarily reduces the amount that physicians are reimbursed for prescribing TAP's product Lupron® to the reimbursement level for a competitor's drug.

In attempting to cloak themselves with the doctrines of standing and exhaustion, Defendants propose a regime that would effectively preclude any review of a new policy imposed on physicians and patients in South Carolina through the use of illegal procedures. The improprieties of Defendants' actions include, but are not limited to, their reliance on a proposed agency rule from 1989 (allowing cost effectiveness as an additional

criterion for coverage of drugs) that was never made final-the same proposed rule that has prompted twenty-four members of Congress to write to HCFA to protest the agency's "extraordinary and unfair" action in attempting to finalize this rule more than seven years late through a process of "[s]tealth rulemaking." Indeed, Congress spoke even more forcefully on the cost effectiveness issue last week, when it enacted a budget bill that promoted cost effectiveness by reducing Medicare reimbursement for drugs and biologics by five percent across the board-while making absolutely no distinction between higher- and lower-priced drugs. See Balanced Budget Act of 1997, H.R. 2015, 105th Cong. § 4556 (enacted July 31, 1997) (amending 42 U.S.C. § 1395u).

Apart from its procedural deficiencies, the LMRP at issue violates substantive federal law and is based wholly on arbitrary and capricious findings of fact. If TAP is barred from bringing the present action, it is highly likely that there will be no judicial review by any court, at any time, of the LMRP at issue. Defendants' suggestion that some unspecified patients may challenge the new policy administratively rings hollow given that the average patient who is being deprived of Lupron® does not live long enough to exhaust the extensive hearing and appellate procedures of the Medicare system that Defendants urge are required before the patient can vindicate his rights in federal court. Fortunately, the doctrines of standing and exhaustion do not dictate Defendants' callous and absurd result, because TAP is an appropriate party to challenge Defendants' illegal and arbitrary actions-actions that are adversely affecting not only TAP but also prostate cancer patients and physicians throughout South Carolina.

Specifically, TAP has the legal right to bring this action because, contrary to Defendants' assertions, TAP will suffer and indeed already has suffered distinct and palpable

injury directly attributable to Defendants' actions. There is no legal basis for the Court to conclude, as Defendants urge, that the actions of physicians affected by Defendants' policy interrupt the causal chain between Defendants' illegal actions and TAP's indisputable injury. There is no legal basis for the Court to find, with respect to Defendants' arguments regarding statutory preclusion, that Congress intended to bar aggrieved manufacturers such as TAP from seeking judicial redress against illegal Medicare rulemaking, given that Congress simply has made no such statement anywhere in the voluminous Social Security Act. Finally, there is no legal basis for the Court to require TAP to exhaust administrative remedies that, by Defendants' own admission, TAP is not authorized to follow.

No doubt aware that their illegal actions will not withstand judicial scrutiny, Defendants have gone to extraordinary lengths in their motion to avoid defending their actions on the merits. For the reasons set forth herein, Defendants' procedural arguments are unfounded, and TAP respectfully requests that the Court deny Defendants' motion to dismiss the Complaint so that the parties may present the merits of this action to the Court.

BACKGROUND

Lupron® is a drug administered by intramuscular injection (injection of liquid directly into the muscle tissue) to treat prostate cancer. It is both reasonable and necessary to use Lupron® in treating certain patients in the final stages of prostate cancer. Accordingly, for over five years, and consistent with HCFA regulations, Palmetto and all other Medicare carriers across the country have reimbursed patients for the average wholesale price ("AWP") of Lupron®. Compl. ¶ 15.

Nearly a decade ago, in January 1989, HCFA proposed a rule that would allow Medicare carriers to use cost as a factor in making coverage determinations as part of

their "reasonable and necessary" determination under section 1861 of the Social Security Act. The "cost-effectiveness analysis" would have applied to coverage of drugs. 54 Fed. Reg. 4302 (Jan. 30, 1989). This rule, however, has never been put into effect. Following a proposal last year by HCFA to finalize this rule, twenty-four members of Congress wrote a strongly worded letter to HHS to protest the fact that "none of the many affected parties will be permitted the opportunity to comment on this new rule":

> Resuscitating a seven-year-old rule and offering no opportunity for contemporaneous comment before it goes into effect flouts the very reason Congress imposed these legal requirements in the first place-to ensure that agencies are responsive to all those affected by the rule.
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> . . . .
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> The federal government should make important public policies in the light of day, not behind closed doors. Stealth rulemaking is unacceptable. Interested parties, the Congress, and the public need to have an opportunity for comments and suggestions. We urge you to abandon this foolish course that HCFA has embarked upon, and to adopt a fair procedure consistent with the purpose of the APA.

Letter from Rep. Christopher Cox et al. to Hon. Donna Shalala 1-2 (Sept. 24, 1996) (appended hereto as Exhibit A and incorporated by reference) (emphasis added).

Nevertheless, in a bulletin dated October 1996, the Medicare Part B carrier for South Carolina (defendant Palmetto) announced an unprecedented policy change: beginning November 1, 1996, Defendants would reimburse physicians who administer Lupron® only up to the AWP of a competitor's product, Zoladex®. The only explanation offered for this change in policy was the conclusory statement that "there is no therapeutic difference between these two agents." Palmetto Gov't Benefits Adm'rs, Medicare Advisory, Oct. 1996, at 32. Acknowledging an inadequate effort to comply with local medical review policy procedures, Palmetto published another notice announcing that the new policy ("the LMRP")

will take effect on May 10, 1997. This notice contained the slightly different but equally conclusory statement that "there is no demonstrable difference in clinical efficacy" between Lupron® and Zoladex®. Palmetto Gov't Benefits Adm'rs, Medicare Advisory, Apr. 1996, at 38. Compl. ¶¶ 16-17.

The notice containing the LMRP provided no support for the carrier's determination that "there is no demonstrable difference in clinical efficacy" between the two products. Indeed, Defendants' determination was not based on any scientific evidence or clinical study that compared the two drugs; Lupron® and Zoladex® are not "equivalents" as that term is used by the Food and Drug Administration or "multiple-source drugs" as that term is used by HCFA in the payment regulation. Compl. ¶ 19.

Accordingly, on April 10, 1997, TAP filed the Complaint in the present action for injunctive and declaratory relief against Defendants. TAP's specific claims are that defendants violated the regulations implementing the Social Security Act (Count I); engaged in rulemaking without notice and comment and without other necessary procedures (Count II); engaged in arbitrary and capricious action (Count III); and violated the Social Security Act itself (Count IV). 1/

Count I states that HHS regulations provide that Medicare payment must be "based on the lower of the estimated acquisition cost or the national average wholesale price of the drug." 42 C.F.R. § 405.517(b) (emphasis added). The LMRP, which purports to authorize reimbursement for Lupron® based not on the average wholesale price of that drug

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1/ Defendants' Memorandum in Support of Motion To Dismiss ("Defendants' Brief") misidentifies the individual counts. See id. at 10.

but on the average wholesale price of a different drug, violates this regulation. Compl. ¶¶ 30-35.

Count II states that the APA and the Social Security Act provide that an agency may promulgate a substantive rule only after interested parties receive notice of the proposed rule and have adequate opportunity to provide comments. 5 U.S.C. § 553; 42 U.S.C. § 1395hh(a)(2), (b). Defendants did not subject the LMRP to proper notice-and-comment procedures. Compl. ¶¶ 36-42.

Count III states that the APA requires a court reviewing agency action to "hold unlawful and set aside agency action, findings, and conclusions found to be . . . without observance of procedure required by law." 5 U.S.C. § 706(2)(D). Defendants did not follow the procedures required by 5 U.S.C. § 553 prior to promulgating the LMRP, which was arbitrary and capricious in that it was based not on any scientific evidence or clinical study that compared the two drugs but on the conclusory, unsupported, and erroneous statement that there is no therapeutic difference between these two agents. Compl. ¶¶ 43-49.

Count IV states that that the Social Security Act provides for Medicare reimbursement of "items or services [that] are reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A). By issuing the LMRP, which added a cost component to the "reasonable and necessary" standard, Defendants violated this statute. As discussed above, although HCFA in 1989 proposed allowing carriers to use cost as a factor in making coverage determinations as part of their "reasonable and necessary" determination, this rule was never made final. Compl. ¶¶ 50-56.

These violations have had an unmistakable impact on TAP, physicians, and prostate cancer patients in South Carolina. Under the LMRP as it took effect on May 10, 1997, South Carolina physicians who continue to prescribe Lupron® are no longer fully reimbursed for the AWP of that drug. Compl. ¶¶ 16-17. The AWP of Lupron® - that is, the statutorily required rate at which physicians historically have been reimbursed for Lupron®-is more than $100 greater than the AWP for Zoladex®, which is the rate at which physicians are now reimbursed for either drug. See Declaration of Richard K. Masterson, Jr. ¶ 3 ("Masterson Decl.") (appended hereto as Exhibit B and incorporated by reference). By switching to Zoladex®, which is reimbursed at its own full AWP, the physicians continue to receive the full AWP of the drug they prescribe, whereas by staying with Lupron®, the physicians' reimbursement falls far short of the AWP of the drug they prescribe.

As expected, in the months since TAP filed its Complaint, many South Carolina physicians have already begun switching from prescribing Lupron® to prescribing Zoladex®. Sales of Lupron® in South Carolina, from approximately the time that physicians had notice that Defendants' policy was going into effect, have decreased by 20%-while sales of Lupron® nationally during the same period have actually increased by 7.5%. See id. ¶ 7.

Contrary to Defendants' suggestions that these physicians have abruptly made an "independent decision" to provide Zoladex®, one that was not "produced by the determinative or coercive effect" of the LMRP, Def'ts' Br. at 14-15, several physicians have specifically stated in their declarations that they were forced to switch because of Defendants' LMRP, which has created a significant economic incentive to prescribe Zoladex® rather than Lupron®. See Declaration of Robert G. McAlpine, Jr., M.D. ¶ 4 ("Dr. McAlpine Decl.")

(appended hereto as Exhibit C and incorporated by reference); Declaration of J. David Rice, M.D. ¶ 5 ("Dr. Rice Decl.") (appended hereto as Exhibit D and incorporated by reference).

In a transparent attempt to protect the improper change in policy from legal challenge, Defendants inserted into the LMRP language permitting the beneficiary to be charged "up to the price difference between the least [sic] costly and the more costly medication." Compl. ¶ 23. Although in this fashion the LMRP technically allows patients to continue to receive Lupron® through paying, by themselves, the shortfall in Defendants' reimbursement for that drug, many of the affected patients simply cannot afford to pay more than the 20 percent co-payment that is already required by Medicare. See Dr. McAlpine Decl. ¶ 5; Dr. Rice Decl. ¶ 7. [2/]

Even if a few patients are willing and able to make up the shortfall in Defendants' reimbursement in order to continue receiving the drug they prefer, the pharmaceutical industry's longstanding practice of giving volume discounts creates a snowball effect that makes it even more difficult for these patients to receive the drug of their choice. That is, the volume discounts associated with ordering large quantities of either drug make it extremely costly for a physician to keep both Lupron® and Zoladex® in stock. See Dr. McAlpine Decl. ¶ 4; Dr. Rice Decl. ¶ 5. It is customary for physicians, especially those with small practices who would not otherwise qualify for volume discounts, to stock and prescribe only one of the two drugs. See Dr. McAlpine Decl. ¶ 4; Dr. Rice Decl. ¶ 5.

2/ Moreover, it is likely that Medicare laws do not allow physicians to charge patients more than the 20 percent co-payment that is anticipated by statutes and regulations. See Compl. ¶ 23. Some physicians have decided not to offer this option to their patients specifically out of fear of violating the Medicare Act, which can lead to civil money penalties. See Dr. McAlpine Decl. ¶ 5; see also infra Part I.A.2.

Before the LMRP was announced, the physicians' overwhelming choice was Lupron®, which has greater patient acceptability in part because it is administered as a liquid suspension rather than as a pellet injected under the skin with a large-bore needle. See Masterson Decl. ¶ 4 (providing statistics on Lupron®'s market share). After the LMRP was announced, however, the cumulative effect of these individual factors has been that a number of large and small urology practices in South Carolina have completely stopped ordering Lupron® from TAP and have begun prescribing Zoladex® to all patients unless they specifically request Lupron® and are able to pay the differential between the physician's reimbursement and the Lupron® AWP. One physician, anticipating the economic effects of the new policy, returned a large quantity of Lupron® almost immediately after receiving notice of the LMRP's publication. See Dr. McAlpine Decl. ¶ 3. In short, TAP's sales of Lupron® have directly suffered and will continue to suffer as a result of Defendants' LMRP.

TAP has also suffered reputational injury from the LMRP. A "Sample Advanced Beneficiary Notice," included in the LMRP for physicians to give to their patients in the event the patient chose to pay the difference, twice contained the erroneous and highly prejudicial statement that "Medicare will deny payment for Lupron" but "will pay for Zoladex." See Palmetto Gov't Benefits Adm'rs, Medicare Advisory, Apr. 1997, at 40 (appended hereto as Exhibit E and incorporated by reference). Defendants' statement that Lupron® is no longer covered by Medicare potentially would be disastrous to TAP in any context, but especially so where the agency is inflicting great economic harm at the same time.

Defendants' actions, grounded in an arrogant disregard of both the substantive Medicare laws and the notice-and-comment procedures required by the Administrative Procedure Act ("APA"), require a judicial response. As the Complaint indicates, Defendants declared that the two drugs are therapeutically equivalent without having the benefit of a head-to-head study and without engaging in more than cursory consultation with the urologists and nurses who prescribe and administer these drugs every day-experts who would have commented that, in addition to substantial patient acceptability issues, the drugs have different rates of action and expose patients to different risks if they are delayed in receiving their regular injections. Procedurally, Defendants effected a significant change in policy in reliance on an eight-year-old proposed regulation that had never been made final and on novel, improper interpretations of existing statutes and regulations.

As a result of Defendants' actions, not only has TAP suffered, but so have the many advanced-stage prostate cancer patients in South Carolina who were successfully managing their illness with liquid injections of Lupron® and now have been confined to using a different drug, previously unknown to them, that requires the subcutaneous injection of a pellet through a large-bore needle. 3/ Moreover, Zoladex®

3/ Lupron® is administered in the form of a liquid suspension containing microspheres that release the active drug, leuprolide, steadily over one to four months. Zoladex®, in contrast, is a pellet the size of a grain of rice that must be injected under the skin. Therefore, the two products require different gauge needles: thin 22-gauge needles for Lupron®, and large-bore 14- and 16-gauge needles for Zoladex®. An abdominal implant inserted with a 14- or 16-gauge needle is more likely to cause occasional complications for patients, such as keloid scarring and bleeding hematoma. Due to the invasiveness of and discomfort caused by the Zoladex® injection, the Zoladex® package insert suggests that, at the physician's or patient's option, a local anesthetic and bandage be used when injecting the pellet. Lupron®, which is administered through a simple intramuscular injection of liquid, does not require these

has a different dosing regimen from Lupron® and exposes patients to different, and potentially greater, risks in the event that the patients are delayed in obtaining their regular injections. Only if the LMRP is rescinded will many of these patients be able to receive the drug that they have chosen to prolong their lives.

STANDARD

On a motion to dismiss under Rule 12(b)(1) for lack of subject-matter jurisdiction, the plaintiff bears the burden of proving that it has standing. FW/PBS, Inc. v. City of Dallas, 493 U.S. 215, 231 (1990). In ruling on a motion challenging standing, however, the trial court "must accept as true all material allegations of the complaint, and must construe the complaint in favor of the complaining party." Warth v. Seldin, 422 U.S. 490, 501 (1975). The trial court may "allow or require the plaintiff to supply, by amendment to the complaint or by affidavits, further particularized allegations of fact deemed supportive of plaintiff's standing." Id.

There is also a "strong presumption that Congress intends judicial review of administrative action." Bowen v. Michigan Acad. of Family Physicians, 476 U.S. 667, 670 (1986). "Only upon a showing of 'clear and convincing evidence' of a contrary legislative intent should the courts restrict access to judicial review." Abbott Lab. v. Gardner, 387 U.S. 136, 141 (1967). Contrary to Defendants' assertion, this presumption is not "reversed," Def'ts' Br. at 32 (emphasis by Defendants), where a statute "provides 'a detailed mechanism for judicial consideration of particular issues at the behest of particular persons.'" Id. (quoting Block v. Community Nutrition Inst., 467 U.S. 340, 349 (1984)). Instead, the presumption favoring judicial review simply "may be overcome" in

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additional procedures. Compl. ¶¶ 20-22.

such circumstances, depending on the inferences that may be drawn from the "statutory scheme as a whole." Block, 467 U.S. at 349.

I. TAP Has Standing To Bring an Action Against Defendants for Their Promulgation of the LMRP.

Standing has two components: constitutional standing, which inquires whether a plaintiff has been injured in fact by the defendants' action, whether the injury is fairly traceable to the defendants' action, and whether the injury is redressable; and prudential standing, which inquires whether the plaintiff's injury is within the zone of interests protected by the statute under which its claims arise. Bennett v. Spear, 117 S. Ct. 1154, 1160 (1997). The only reported case that has directly addressed the issue of a manufacturer's standing to sue for illegal Medicare rulemaking, Ioptex Research v. Sullivan, 1990 WL 284512 (C.D. Cal. Dec. 10, 1990) (opinion appended hereto as Exhibit F), has held that a manufacturer does in fact have standing to challenge such actions under the APA. Id. at *4. Defendants' Brief fails even to cite, let alone distinguish, Ioptex. In the present case, as in Ioptex, the plaintiff's injury satisfies both the constitutional and prudential standing tests and consequently allows the plaintiff to bring this action. See infra Part I.B (discussing Ioptex in detail).

A. TAP's Suit Meets the Three-Part Test for Constitutional Standing.

Defendants argue that TAP faces only the threat of "wholly conjectural" injury as a result of their LMRP-and, in the alternative, that "any injury TAP may suffer" would be caused by the "independent" actions of physicians in derogation of their ethical duties to patients. See Def'ts' Br. at 12-15. Neither argument has a basis in the

facts, which show beyond dispute the sales that TAP has lost as a direct result of Defendants' LMRP.

1. TAP Has Already Suffered Concrete Harm, and Additional Harm Is Threatened.

To satisfy the injury-in-fact test of constitutional standing, the law requires only that the plaintiff suffer a "distinct and palpable injury." Shanty Town Assocs. Ltd. Partnership v. EPA, 843 F.2d 782, 788 (4th Cir. 1988). For the reasons discussed at length above and in the attached Declarations, TAP has already suffered distinct and palpable financial injury in South Carolina, Masterson Decl. ¶ 7, and more such harm is threatened. If Defendants' LMRP is not set aside, TAP will be forced either to lower its prices permanently to the Zoladex® level or to continue to lose market share. These allegations cannot seriously be questioned, as they are a matter of "basic economic logic": if the unreimbursed portion of the price of Lupron® to physicians is driven up, orders of Lupron® will decrease. Cf. United Transp. Union v. ICC, 891 F.2d 908, 913 n.7 (D.C. Cir. 1989) ("The allegation that the court accepted as true in [another standing case] was not just plausible, it was an application of basic economic logic. Indeed, courts routinely credit analytically identical allegations in garden-variety competitor standing cases.").

Moreover, TAP has suffered direct reputational injury as a result of Defendants' statement to at least one physician that the portion of one three-month injection attributable to the third month injection constituted "non-covered services," as well as Defendants' statements in the Sample Advanced Beneficiary Notice that "Medicare will deny payment for Lupron" but "will pay for Zoladex," wrongly indicating

that Lupron® would be completely non-covered (as opposed to insufficiently covered) under the LMRP. Compl. ¶ 25. Statements of this nature cause drastic injury to TAP to the extent they erroneously suggest to TAP's customers that Lupron® has been removed from the list of Medicare-approved drugs.

2. Physicians' Prescription Patterns Have Changed as a Direct, Inevitable Consequence of Defendants' LMRP.

The law requires that the plaintiff's injury be "fairly traceable" to the defendants' action. Lujan v. Defenders of Wildlife, 504 U.S. 555, 560 (1992). The case on which Defendants rely most heavily, Bennett v. Spear, 117 S. Ct. 1154 (1997), solidly supports TAP's position. In Bennett the Supreme Court this year found that an APA plaintiff had standing despite the defendant's argument that traceability was negated where the "proximate cause" of the plaintiff's injury was the act of a third party. See id. at 1164. The Court held that such a reductionist view "wrongly equates injury 'fairly traceable' to the defendant with injury as to which the defendant's actions are the very last step in the chain of causation." Id. As an example of what sort of agency action would meet the traceability test, the Court cited "injury produced by determinative or coercive effect upon the action of someone else." Id. 4/

It is obvious that at least some percentage of the physicians who have their reimbursement rates for one drug abruptly lowered will turn to a competitor's drug. So

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4/ It is difficult in any event to see how Defendants can logically draw an anti-standing inference from a case in which the plaintiff was found to have standing; at most, Bennett stands for the proposition that traceability exists where there is determinative or coercive effect, and Bennett is simply indeterminate on cases where the causal relationship is weaker. In other words, Bennett found that determinative or coercive effect is sufficient but not necessary to establish standing.

it is quite surprising that Defendants have tried to focus the blame for TAP's injury away from their illegally promulgated LMRP and onto the physicians themselves by implying that it is unethical for a physician to take his own costs into consideration when prescribing medication. The laws of medical ethics surely do not require a physician to contribute his own money to help his patients pay for the best possible treatment regardless of the cost of that treatment.

The passage that Defendants quote from Professor Rodwin does not contradict this obvious point. See Def'ts' Br. at 16 & n.9 (quoting Marc A. Rodwin, Strains in the Fiduciary Metaphor, 21 Am. J.L. & Med. 241, 246 (1995)). First, Professor Rodwin's article is not and does not even purport to be an authoritative blanket statement of medical ethics. Second, the very point of the Rodwin article is that, although there may at times be ethical conflicts between physician and patient, the law provides no remedy for physicians' breach of fiduciary duty except in narrow circumstances that are not at issue here. See Rodwin, supra, at 247-48 ("Aside from limited circumstances, physicians-as clinicians-are not held to fiduciary standards, especially with respect to financial conflicts of interest."). There is no legally cognizable action for a physician's failure to resolve "conflicts between the physician's and the patient's [financial] interest 'to the patient's benefit,'" as Defendants imply. Def'ts' Br. at 16 (quoting Rodwin, supra, at 246).

The plain fact is that the LMRP does coerce, or produce a determinative effect upon, physicians. In the face of the government's fiat that the additional cost of administering Lupron® is not reasonable and necessary, Compl. ¶ 24, a physician who, for reasons discussed above, would otherwise choose to prescribe Lupron® is left with no

choice. If the patient cannot afford to pay for the difference in cost between Lupron® and Zoladex®, the physician must accept the government's determination and provide his patient with Zoladex®.5/ The government, in such a circumstance, cannot be heard to say, however, that such a physician has an ethical obligation to choose a course of treatment that the government itself has said is unnecessary. It is the government that has told the physician that the administration of Lupron® is not reasonable and necessary. Under these circumstances it is obvious that the government's action coerces the physician's reaction. The LMRP is designed to do just that, and the government cannot plausibly maintain that an instruction addressed to physicians does not have a determinative effect upon their actions.

Moreover, the case law that Defendants cite for the proposition that physicians must act in patients' best interests and exercise independent medical judgment-propositions that in themselves are logically irrelevant to the issue of traceability-was developed in a completely different context. See Def'ts' Br. at 12, 15. In all four cases cited, the courts were determining whether a government physician was an employee or an independent contractor of the government for purposes of the Federal Tort Claims Act and the state action doctrine. Blum v. Yaretsky, 457 U.S. 991, 1008

5/ As noted in the Complaint, even where the patient agrees to pay the additional cost, the physician faces a dilemma. Medicare law requires physicians who accept assignment of Medicare claims to charge only the Medicare-allowed amount for a physician service, which includes the administration of drugs. Physicians who do not accept assignment are also restricted in the amount they may charge for a covered service. Compl. ¶ 24. Civil penalties are imposed for violation of these provisions. 42 U.S.C. §§ 1395u(B)(3)(B)(ii), 1395w-4(g). Although the LMRP states that physicians may charge patients the difference in price between the two drugs, nowhere does the statute authorize the physician to ignore the limiting charge provisions in such a case, and the uncertainty in this area means that some physicians will choose not to risk the penalties and will instead switch to Zoladex®. See Dr. McAlpine Decl. ¶ 5.

(1982); Robb v. United States, 80 F.3d 884, 889 (4th Cir. 1996); Ezekiel v. Michel, 66 F.3d 894, 902 & n.14 (7th Cir. 1995); Quilico v. Kaplan, 749 F.2d 480, 483-84 (7th Cir. 1984). The authors of these opinions, unlike the Defendants in the present action, do not presume to tell us whether physicians must act without regard for their own economic situation.

In fact, other cases have recognized the coercive effect that cost-conscious reimbursement regulations can have on physicians' practices. In American Medical Association v. Mathews, 429 F. Supp. 1179, 1188-90 (N.D. Ill. 1977), a group of physicians challenged maximum-allowable-cost Medicare regulations that limited federal reimbursement to the cost of the least expensive multiple-source drug. The physicians alleged that the regulations would effectively compel them to prescribe the least expensive drug even though they would otherwise prescribe another drug which they believe to be safer, more reliable or more effective. Id. The court agreed, holding that the physicians had standing to challenge the regulations even in the absence of direct financial injury because the disputed drug reimbursement limitations interfered with the physicians' exercise of independent medical judgment. Id. at 1190-91.

Similarly, in American Society of Cataract and Refractive Surgery v. Sullivan, 772 F .Supp. 666, 669 (D.D.C. 1991), vacated on other grounds, 986 F.2d 546, 1993 WL 30258 (D.C. Cir. 1993), a group of ophthalmologists challenged a rule restricting Medicare coverage of investigational cataract surgery, claiming the rule would force them to prescribe other cataract surgery even where they believed the investigational surgery to be preferable treatment. The court held that the ophthalmologists had standing to challenge the rule because "[t]he rule would limit

physicians' ability to prescribe for their patients the best available course of treatment." Id. The court clearly recognized the coercive effect of the rule, stating:

> In cases where an investigational [cataract surgery] is, in the professional judgment of a treating physician, the preferred device, economics would nonetheless dictate use of an inferior [surgery]. Patients would be able to obtain state-of-the-art treatment only if they are able and willing to pay for the new device themselves.

Id.

3. TAP's Injury Would Be Redressed by the Relief TAP Seeks.

As Defendants have noted, the redressability analysis largely overlaps with the traceability analysis. Def'ts' Br. at 17 (citing Allen v. Wright, 468 U.S. 737, 757 (1984)). Several physicians have indicated that, if the LMRP is rescinded, they are very likely to switch their old Lupron®-to-Zoladex® patients back to Lupron®. See Dr. McAlpine Decl. at ¶ 7; Dr. Rice Decl. at ¶ 8. More importantly, rescission of the LMRP would prevent future physicians from switching away from Lupron® in the first place. Because TAP will, absent relief, continue to suffer injury traceable to Defendants' action, and because TAP has requested that the Court enjoin this action and prospectively declare it illegal, the requested remedies would undoubtedly redress TAP's future injury. See United States v. Students Challenging Regulatory Agency Procedures, 412 U.S. 669, 689-90 (1973) (finding redressability where plaintiffs alleged a much more attenuated causal connection between judicial action and relief).

B. Because Congress Did Not Intend To Preclude Actions by Manufacturers, TAP Meets the Test for Prudential Standing.

The zone of interests test "is not meant to be especially demanding," and "there need be no indication of congressional purpose to benefit the would-be plaintiff." Clarke v. Securities Indus. Ass'n, 479 U.S. 388, 399 (1987). Defendants argue that manufacturers such as TAP lie outside the zone of interests of the Social Security Act. Defendants' argument, woven entirely from cases that do not involve manufacturers, directly contradicts the case law addressing the zone of interests issue in the context of a manufacturer suing over Medicare rulemaking: Ioptex Research v. Sullivan, 1990 WL 284512 (C.D. Cal. Dec. 10, 1990).

In Ioptex, the court considered whether a manufacturer of intraocular lenses ("IOLs") had standing to challenge a Medicare regulation that established the reimbursement rate for the IOLs. Id. at *1. As here, the defendants argued that the manufacturer did not have standing because it was not in the zone of interest of the Medicare Act. Id. The court disagreed, first noting that "the purpose of Medicare is 'to make the best of modern medicine more readily available to the aged.' " Id. at *2 (quoting S. Rep. No. 89-404 (1965)). The court also noted the manufacturer's desire to provide to beneficiaries a product designed to benefit many elderly Americans and concluded that the manufacturer's "interest in gaining wider distribution of its IOLs is not inconsistent with or only marginally related to the Medicare Act's purpose." Significantly, the court fully acknowledged that the manufacturer's motivation "may be primarily commercial"; however, the court concluded that "this does not change the fact that [the manufacturer's] interests are clearly aligned with those of the Medicare

beneficiaries and providers." Id. The court also determined that the fact that Congress did not explicitly include manufacturers in the Medicare remedial scheme was not evidence of an intent to preclude judicial review by manufacturers. Id. at *3.

The rationale and holding of Ioptex are equally applicable in this action. TAP wants to make readily available to Medicare beneficiaries a product overwhelmingly preferred by physicians and patients alike. This interest clearly dovetails with Medicare's purpose of making "the best of modern medicine more readily available to the aged." The commercial nature of TAP's interest should not preclude TAP from obtaining review of an LMRP that is now denying Medicare recipients "the best of modern medicine."

An analogous case that further supports TAP's standing is Berlex Laboratories v. FDA, 942 F. Supp. 19 (D.D.C. 1996), in which the United States District Court for the District of Columbia addressed whether the manufacturer of one drug had standing to challenge the FDA's approval of another drug under the Public Health Service Act ("PHSA"). The court acknowledged that Congress did not enact the PHSA to protect a manufacturer's economic interest and that the plaintiff manufacturer's action was obviously driven by the manufacturer's "economic interest in maintaining [its product's] market position." Id. at 24. Nevertheless, the court held that the manufacturer had standing. Id. The court was persuaded that because the manufacturer was attempting to ensure that the FDA's approval was proper, its interests were sufficiently aligned with those of the intended beneficiaries of the PHSA. Id. at 25.

As with the plaintiff manufacturer in Berlex, here TAP is uniquely motivated and well situated to ensure that Defendants do not arbitrarily deny Medicare

beneficiaries access to "reasonable and necessary" treatment. TAP is therefore within the zone of interests of the Medicare Act and has standing to bring this challenge.

Finally, according to Defendants' own arguments, a holding that TAP is precluded from suing due to a lack of prudential standing would leave Defendants' actions virtually immune from judicial review. The average patient on Lupron® has a life expectancy of approximately 30 months. The review process established by the Medicare statute has five mandatory levels for patient-petitioners, including carrier review of its fair determination, carrier fair hearing, administrative law judge ("ALJ") hearing, Appeals Council review, and finally federal court review. The first four steps alone could take several years to complete, making Defendants' acts effectively impossible for this proposed class of plaintiffs to review.

Contrary to Defendants' assertions, TAP is not trying to do an end run around the rules or to obtain a "broader and quicker right of review than that afforded to Medicare beneficiaries." Def'ts' Br. at 28. TAP is pursuing a remedy-injunctive and declaratory relief against improper rulemaking-that is completely different from the money damages sought by a patient aggrieved by an adverse individual determination of benefits. The difference between the remedies at issue, and the different nature of the two claims, are so stark as to make the two claims literally incomparable.

II. The Doctrine of Exhaustion Does Not Bar TAP's Claim.

Defendants' sketchy argument about exhaustion completely misconstrues the structure and purpose of the Social Security Act. The administrative procedures prescribed by that Act were established to channel the extremely numerous, fact-specific challenges of Medicare beneficiaries who are disputing the amount of individual claims.

Nowhere do these administrative procedures provide a mechanism for challenging the legitimacy of the regulatory authority (such as HCFA's regulations or the carrier's LMRPs) that provides the basis for the beneficiaries' claims. Neither a carrier hearing officer nor an ALJ has the authority to strike down an LMRP; their actions have no precedential value. Accordingly, viewing this situation in the context of the exhaustion doctrine, it would be futile for TAP to bring the present claim before the hearing officers and ALJs described in the Social Security Act, because such officers would have no authority to grant the relief requested in this case, that is, to order Defendants to rescind the illegal LMRP.

A. The Law of this Circuit Does Not Require Exhaustion of Social Security Act Procedures in Medicare Part B Disputes over the Legitimacy of Regulations.

Defendants have conceded that the administrative remedies of the Social Security Act are unavailable to manufacturers such as TAP. Def'ts' Br. at 23 ("TAP has not exhausted-and cannot exhaust-administrative remedies...."); see also Ioptex, 1990 WL 284512 at *3 (authorizing direct judicial review because Ano provision is made for [Medicare Part B administrative] challenges by manufacturers such as Ioptex."). It would obviously be futile to require TAP to exhaust remedies that it is barred from pursuing. Therefore, exhaustion is simply not an issue in this case. [6]

6/ To the extent that it even discusses exhaustion, however, Defendants' Brief misstates the current law. Defendants state that, since 1986, "Courts of Appeals" have held that Medicare Part B claims require exhaustion of administrative appeals. Def'ts' Br. at 24 (citing Martin v. Shalala, 63 F.3d 497, 503 (7th Cir. 1995); Abbey v. Sullivan, 978 F.2d 37, 42-43 (2d Cir. 1992); National Kidney Patients Ass'n v. Sullivan, 958 F.2d 1127, 1130-34 (D.C. Cir. 1992)). What Defendants omitted to mention, however, is that courts in the First, Third, and Ninth Circuits have found that challenges to the methodology by which Medicare Part B

Furthermore, to the extent that the doctrine of exhaustion is based on the policy of giving the agency the "opportunity to 'correct its own mistakes before it is haled into federal court,'" Volvo GM Heavy Truck Corp. v. United States Dept. of Labor, 1997 WL 359337 at *3 (4th Cir. July 1, 1997) (opinion appended hereto as Exhibit H), it is important to note that TAP has done everything short of attempting to enter the administrative procedures from which it is plainly barred. TAP wrote to agents of the Defendants at all levels and gave the agency a chance to cure the defects of the LMRP extrajudicially. See Compl. ¶ 29 (summarizing TAP's pre-litigation correspondence with the Secretary of HHS, the Director of the Bureau of Policy Development at HCFA, the Acting Regional Director of HCFA, and the Medical Director of Palmetto).

B. Congress's Provision of an Administrative Remedy to Patients Does Not Preclude Administratively Excluded Plaintiffs from Seeking Judicial Relief.

The doctrine of statutory preclusion, which does not fit neatly under the rubric of standing or exhaustion, is somewhat like standing because it attempts to bar suit outright by virtue of the plaintiff's identity and also because it overlaps with the "zone of interests" analysis of prudential standing, both being based on congressional intent.

Defendants argue, based on Block v. Community Nutrition Inst., 467 U.S. 340 (1984), that Congress, by identifying beneficiaries as the only parties who may seek

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determinations are made or the legitimacy of Medicare Part B rulemaking do not require exhaustion. See, e.g., American Ambulance Serv. v. Sullivan, 911 F.2d 901, 902 (3d Cir. 1990); McCuin v. Secretary of HHS, 817 F.2d 161, 164B66 (1st Cir. 1987); Stewart v. Sullivan, 816 F. Supp. 281, 287 (D.N.J. 1992); Pulmocare Pharmacy v. Sullivan, No. 91-1291-PA, 1992 WL 226932 at *4 (D. Or. 1992) (opinion appended hereto as Exhibit G); Ioptex, 1990 WL 284512 at *3. To TAP's knowledge, the Fourth Circuit has not ruled on the issue.

recourse to the administrative process of the Social Security Act, intended to bar manufacturers from bringing challenges to Medicare rulemaking in court. In Block, however, the administratively excluded plaintiff was attempting to bring precisely the same sort of challenge that was specified in the statute. One commentator explains:

> Block v. CNI is a peculiar "preclusion" case. The challenged actions are fully reviewable, just not at the behest of these parties. Hence, it might be more appropriate to view Block v. CNI as involving one of those rare instances in which Congress has denied standing to a particular subset of parties who may be adversely affected by official action.

Jerry L. Mashaw et al., Administrative Law 797 (3d ed. 1992). Here, in contrast, TAP is bringing a challenge wholly unlike the sort authorized by statute: a challenge to Defendants' rulemaking as opposed to a challenge to their individual determination of benefits in a discrete case.

Defendants' preclusion argument makes no sense because it would essentially leave improperly promulgated Medicare rules insulated from challenge, or at best would require some unspecified plaintiff first to exhaust pointless administrative remedies that are incapable of providing the relief requested. Ioptex, the only reported manufacturer case to address this issue directly, makes clear that manufacturers are not precluded in this manner:

> The Secretary has attempted to transform congressional silence into a "fairly discernible" intent to preclude judicial review. However, the Secretary fails to differentiate between the types of issues that are subject to the detailed administrative scheme set up by Congress and the issues raised by plaintiff's suit....[T]he provision of a remedial scheme available to certain groups for certain types of disputes should not be interpreted as precluding judicial review of a different type of dispute at the instance of an administratively excluded plaintiff.

Ioptex, 1990 WL 284512 at *3 (emphasis added). Here, TAP is precisely such an "administratively excluded plaintiff."

Defendants further argue that Congress has stripped the Court of its power to redress TAP's injury because only Defendants themselves have the "expertise necessary 'to illuminate and resolve' disputes in this highly technical area of the law." Def'ts' Br. at 27. Yet this case is, at bottom, a generic APA challenge to improper agency rulemaking. APA analysis is precisely, and even uniquely, within the federal courts' expertise; this action requests review of the legitimacy of Defendants' statutory and regulatory interpretations, the sufficiency of Defendants' effort (or lack of effort) to follow notice-and-comment rulemaking, and the arbitrariness of Defendants' procedure for fact-finding with respect to the therapeutic equivalence of the two drugs. See Christopher W. v. Portsmouth Sch. Comm., 877 F.2d 1089, 1095 (1st Cir. 1989); Mrs. W. v. Tirozzi, 832 F.2d 748, 759 (2d Cir. 1987) ("[C]ourts seldom defer to an administrative agency when the issue involved is purely a legal question not involving either administrative expertise or experience."). TAP's action does not request a de novo review of the scientific merits of two drugs, or of some individual beneficiary's claim for reimbursement under legitimate Medicare rules.7 In sum, there is no practical or legal reason for the Court to refrain from deciding the issues raised by this action.

7/ Defendants cite Thomas Jefferson University v. Shalala, 512 U.S. 504 (1994), and Mowbray v. Kozlowski, 914 F.2d 593 (4th Cir. 1990), for the proposition that Defendants alone have the "expertise necessary" for this "highly technical area of the law." Def'ts' Br. at 27. Yet the cited passages of Thomas Jefferson and Mowbray are completely inapposite because they deal not with standing but with judicial deference to agency interpretation on the merits of the action. See Thomas Jefferson, 512 U.S. at 512; Mowbray, 914 F.2d at 598. Regardless of the value of Chevron deference, Defendants have provided no authority for the untenable proposition that courts are so inexpert that they must preemptively keep themselvesCusing the doctrine of standing or statutory preclusion - from even getting to the merits.

For the foregoing reasons, TAP respectfully requests that the Court deny Defendants' motion to dismiss the Complaint. TAP further requests that the Court exercise its discretion under Local Rule 12.08 to hear oral argument on Defendants' motion.

Respectfully submitted,

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